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Submittal and Incorporation of Data to the Technical Data Management System
Quality Implementing Procedure ID: OSTI-LLNL-QIP-SIII.3, Rev.0, Mod.0

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Disclaimer

SUBMITTAL AND INCORPORATION OF DATA TO THE TECHNICAL DATA MANAGEMENT SYSTEM

Quality Implementing Procedure ID: OSTI-LLNL-QIP-SIII.3 Rev. 0, Mod.0   *Effective:* 2/25/05

1. PURPOSE

This Quality Implementing Procedure (QIP) establishes the responsibilities and process for preparing data for future submittal and incorporation in the Technical Data Management System (TDMS) in accordance with the OSTI-LLNL Quality Assurance Plan (QAP) which implements the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P, Supplement III, Section III.2.

2. SCOPE

This QIP applies to individuals within the Office of Science & Technology and International (OSTI)-Lawrence Livermore National Laboratory (LLNL) Project, and other participants who prepare key technical data that will be submitted to the TDMS in support of the OSTI-LLNL Project. This procedure has been prepared in accordance with OSTI-LLNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures.*

For the purpose of this procedure, key technical data refer to a subset of all data obtained throughout the OSTI-LLNL scientific investigation that may be used to characterize and license a high-level nuclear waste geologic repository.

Forms and guidance from Administrative Procedure AP SIII.3Q, *Submittal and Incorporation of Data to the Technical Data Management System*, have been referenced herein. However, this QIP does not require a direct interface with the TDMS maintained by BSC. All data developed as a result of OSTI-LLNL scientific investigation will be stored at LLNL until such time as turnover requirements are provided by OCRWM/OSTI. The use of forms processes, guidance, etc. from AP SIII.3Q is intended solely to aid in the actual submittal and incorporation of data to the BSC TDMS when authorized by OCRWM/OSTI. At that time an additional QIP or a revision to the QIP will be issued to control the turnover of data.

3. PROCEDURE

3.1 Origination of Key Technical Data

3.1.1 The OSTI-LLNL Principal Investigators (PIs) or technical staff (referred to as the Data Originator) shall derive OSTI-LLNL key technical data from scientific investigations controlled by the scientific notebooks in accordance with OSTI-LLNL-QIP-SIII.0, *Scientific Notebooks*, Technical Implementing Procedures

(TIP) or other applicable QIPs (e.g. OSTI-LLNL-QIP-2.2, *Planning for Science Activities,* OSTI-LLNL-QIP-SIII.1, *Technical Reports,* OSTI-LLNL-QIP-SIII.2, *Model Reports,* etc.)

3.1.2 All OSTI-LLNL key technical data shall be tracked by the OSTI-LLNL Technical Data Tracking (LTDT) System.

3.2 Incorporation of Metadata to the Automated Technical Data Tracking (ATDT) Database

3.2.1 The **Data Originator** shall:

A. Ensure that controls specified in OSTI-LLNL-QIP-SV.0, *Management of OSTI-LLNL Electronic Data,* have been addressed.

B. Provide all required data information to the Technical Data Coordinator. For developed data, clearly identify direct sources (Technical Information Center [TIC] Catalog Numbers, TDMS Data Tracking Numbers [DTN], OSTI-LLNL Record Center [RC] Accession/Package Numbers, etc.).

C. Complete a "Key Technical Data Traceability" Form (Attachment 1) which provides traceability to the supporting data (that is, references the applicable scientific notebooks and page numbers, photographs, maps, computer files, etc.).

D. Clearly identify all records for the submittal package as dictated by the originating procedure. Provide records-related information to the Technical Data Coordinator for use in completion of the Electronic Records Road Map at a later date in accordance with AP-SIII.3Q, *Submittal and Incorporation of Data to the Technical Data Management System.*

E. Submit sample number verification documents for any data that were created using or relying on samples that are tracked at the Sample Management Facility (SMF). These documents must include reference to those samples. Include the reference to those samples in the form of either of the following:

   1. E-mail from the SMF verifying that the sample numbers provided exist in the SMF

   OR

   2. A verification report created using the SMF sample verification tool available at the TDMS intranet site.

F. If Qualified data are Acquired or Developed, and are not Product Output a comprehensive index of affiliated records must be produced. Provide the record identification information to the Technical Data Coordinator.

3.2.2 The **Technical Data Coordinator** shall complete the initial incorporation of the data information (metadata) for all key technical data using the following steps:

A. Assign a data tracking number (DTN) to the data using the format LLXXXXOSTIYYYY.YYY, where LL identifies LLNL and the twelve character "XXXXOSTIXXXX" is a unique code that lists the year and month of the submittal, identifies OSTI and the remaining alphanumeric characters are specific characters that may identify each data set (e.g., LL0404OSTIECRB.001)

B. Complete the Technical Data Information Form (TDIF) in accordance with AP-SIII.3Q.

C. If the data information provided by the Data Originator indicates that a supersession, a qualification downgrade, or editorial correction to an existing data set is required, an Impact Review Action Notice (IRAN) (Attachment 2) shall be initiated prior to processing the request.

   1. Coordinate supersession effort with applicable TDMS Database Administrators (DBAs).

   2. Initiate an IRAN(s) in accordance with Section 3.3.

D. Notify the ATDT DBA that the incorporation of the metadata has been completed and provide copies of the initiated IRAN(s) for supersessions or qualification downgrades to the ATDT DBA and the Records Coordinator.

E. Print a hard copy of the TDIF form and process the data submittal package through the Records Coordinator in accordance with Section 4.

3.2.3 Changes to the TDIF

For changes to an existing ATDT entry, the **Technical Data Coordinator** shall:

A. Contact the ATDT DBA to make the ATDT Entry Screen available to accept changes.

B. Enter necessary changes to existing metadata.

C. Ensure all modifications/corrections to the metadata are documented in the appropriate ATDT Entry Screen field in accordance with AP-SIII.3Q. Changes to the comments/description fields must be annotated with the date of the change. Document which TDIF fields were changed in the ATDT Change History Table.

D. Notify the ATDT DBA that changes have been completed.

E. Forward the updated TDIFs (including TDIFs revised due to superseded data) to the Records Coordinator for submittal to the RC per Section 4.

3.2.4 Superseding and Superseded Data

The PI or designee shall treat data that supersede previously submitted data as new data submittal and provide the Technical Data Coordinator with all required metadata information. The **Technical Data Coordinator** shall identify superseding and superseded DTNs in the ATDT database, as follows:

A. In accordance with information provided by the data Originator, identify data that supersede data previously reported in ATDT database with the new DTN(s).

B. Identify the superseded DTN(s) on the ATDT Entry Screen by including the statement *"These data supersede data previously identified by DTN(s): (insert DTN(s) of superseded data)"* in the Description field and by entering the superseded DTN(s) in the Supersedes DTN field.

C. Describe the difference between the superseded and superseding data in the Comments field of the superseding DTN ATDT Entry Screen.

D. Contact the ATDT DBA to make the ATDT Entry Screen of the superseded TDIF available to accept changes.

E. Modify superseded TDIF on the ATDT Entry Screen in the ATDT database with the statement *"These data have been superseded by data identified with DTN(s): (insert DTN(s) of superseding data)"* in the Description of Data field and by entering the superseding data DTN(s) in the Superseded by DTN field. This modification of existing metadata also requires documentation in the Comments field and the ATDT Change History Table.

F. Describe the difference between the superseded and superseding data in the Comments field of the superseded DTN ATDT Entry Screen.

G. Notify the ATDT DBA that changes have been made.

3.3 Initiating and Completing Data Impact Reviews

3.3.1 The **Data Originator** and/or **Technical Data** Coordinator shall initiate an impact review of the data supersession, qualification downgrade, or editorial correction and identify the technical or model reports or data that have used the data as input and may be potentially impacted/affected.

The **Technical Data Coordinator** shall:

A. Create IRAN forms for potentially impacted data, and/or technical/model reports and send forms to the Affected PI(s).

B. If no affected data or reports are identified, document on the IRAN form and proceed to Section 3.3.4.

3.3.2 The **affected PI** shall perform (or designate a qualified technical staff to perform) the impact evaluation as follows:

A. Review potentially impacted data and/or technical/model reports listed on the IRAN form. Results of the review could include the following:

1. No impact identified.

2. Revision or change of an impacted technical/model report or developed data set is not needed because the effect on technical results is not significant. Include an explanation of the reason the effect on technical results is not significant.

3. Revision or change of an impacted technical/model report or data is needed.

     • Determine if the impact is within the OSTI-LLNL Project requirements and work scope, cost, and schedule baselines, and is part of the normal evolution of the product as currently scheduled.

     OR

     • If not within the baseline, identify additional work to be performed and request the OSTI-LLNL PM's approval prior to performing any additional work.

B. Document the results of the impact evaluation on the IRAN form.

C. If additional work to the affected data and/or technical/model report has been identified, inform the OSTI-LLNL PM (or designee) and ensure appropriate actions are taken to document the additional work.

D. Enter printed name, signature, and date and forward the IRAN form(s) to the Affected PI or to the OSTI-LLNL Project Manager (or designee) (if the Affected PI was the Reviewer) for signature.

3.3.3 The **Affected PI** or **Project Manager** (or designee) (if the Affected PI was the Reviewer) shall sign the IRAN form indicating approval of the impact review results and return the IRAN form to the Technical Data Coordinator for incorporation in the Comments field of the superseding and superseded DTN TDIFs.

3.3.4 If no affected organizations or disciplines were identified on the IRAN the **Data Originator** shall sign the IRAN form and provide relevant IRAN information to the Technical Data Coordinator for incorporation in the Comments field of the superseding and superseded DTN TDIFs. Provide IRAN tracking numbers

and other information to provide traceability and transparency throughout the supersession.

3.4 Documentation of Errata

Upon receipt of errata documentation generated in accordance with OSTI-LLNL-QIP-16.0, *Condition Reporting and Resolution*, the **Technical Data Coordinator** shall add a note to the description section of the TDIF for the affected DTN making reference to the errata information. Include errata number, document identifier, date, and records information, if applicable.

4. RECORDS

The records listed below shall be collected and submitted to the Records Coordinator in accordance with OSTI-LLNL-QIP-17.0, *Records Management,* as individual records or included in a records package, as specified.

4.1 QA Records

The following records are submitted by the Technical Data Coordinator in accordance with this and/or relevant data generating procedure(s):

> For Q-Data submittals:
>
>> Subject data and associated supporting documentation (compiled and formatted as required by this procedure)
>>
>> Notification of submittal rejection from TDMS or communication of reason for non-submittal of data, if applicable
>>
>> Record Road Map, if applicable
>>
>> Technical Review of Data
>>
>> Completed IRAN(s), if applicable
>>
>> Key Data Traceability Form
>>
>> TDIF

4.2 Non-QA Long-Term Records

The following records are submitted by the Technical Data Coordinator in accordance with this and/or relevant data generating procedure(s):

> For Non-Q Data Submittals:
>
>> Subject data and associated supporting documentation (compiled and formatted as required by this procedure)

Notification of submittal rejection from TDMS or communication of reason for non-submittal of data to TDMS, if applicable

Record Road Map, if applicable

Technical Review of Data

Completed IRAN(s), if applicable

Key Data Traceability Form

TDIF

4.3 Non-QA Short-Term Records (three years or less retention)

Cover Letter

Acceptance Notification from TDMS DBA

5. RESPONSIBILITIES

5.1 The **Project Manager (PM)** (or designee) is responsible for assigning PIs/Data Originators to complete the data acquisition or development, review and submittal to the TDMS; for the approval of any proposed, additional work related to IRAN resolution; and for final disposition of disputed review comments.

5.2 The **Data Originator** is responsible for preparing the data package, and for responding to the review comments.

5.3 The **Technical Data Coordinator** is responsible for overseeing the submittal of Data to the LTDT, for scheduling and coordinating the review process, including initiating IRAN(s), as appropriate.

6. ACRONYMS AND DEFINITIONS

6.1 ACRONYMS

ATDT	Automated Technical Data Tracking
DBA	Database Administrator
DOE	U.S. Department of Energy
DTN	Data Tracking Number
IRAN	Impact Review Action Notice
LLNL	Lawrence Livermore National Laboratory
LTDT	LLNL Technical Data Tracking
OCRWM	Office of Civilian Radioactive Waste Management
OSTI	Office of Science & Technology and International
PI	Principal Investigator
PM	OSTI-LLNL Project Manager

QA	Quality Assurance
QAP	Quality Assurance Plan
QARD	Quality Assurance Requirements and Description
QIP	Quality Implementing Procedure
RC	Records Center
SMF	Sample Management Facility
TDIF	Technical Data Information Form
TDMS	Technical Data Management System
TDP	Technical Data Parameter
TIC	Technical Information Center

6.2 DEFINITIONS

Accession Number: A unique identifier assigned by the Records Center (RC) to each indexed program record.

Corroborating Data: Data that are used to support or substantiate other data (QARD). The use of corroborating data has no impact on the qualification status of the supported data because they are not used in the direct formulation of the arguments or datasets.

Data (collected): Factual information obtained from investigation activities such as sample collection, physical measurements, testing, and analyses both in the field and in the laboratory (QARD). For the purposes of this procedure, this type of information is considered acquired data.

LLNL Technical Data Tracking (LTDT) Database: An information management system designed to track data resulting from OSTI data acquisition and development activities.

Technical Data Coordinator: A qualified individual identified by the OSTI-LLNL Project Manager (PM) who submits data to the TDMS after they are compiled and formatted by the Data Originator.

Data Originator: Individual responsible for collecting, developing, assembling and submitting key technical data to the TDMS.

Data Reduction: Processes that change the form of expression, quantity of data or values, or the number of data items (QARD). For the purposes of this procedure, this type of information is considered developed data.

Data Tracking Number (DTN): A unique identifier assigned by the Technical Data Coordinator to each data set tracked in the LTDT Database to ensure traceability throughout the life of the data. OSTI-LLNL DTNs use the format "LLXXXXOSTIYYYY.YYY," where LL=LLNL, the twelve character "XXXXOSTIXXXX" is a unique code that lists the year and month of the submittal, identifies OSTI; the remaining alphanumeric characters are specific characters that may identify each data set.

Database Administrator (DBA): A qualified individual assigned the responsibility to maintain the functionality of a database and incorporate specific subject matter data into the database within the TDMS.

Editorial Correction: The process to repair a minor error found within the contents of the key technical data submittal package after the data have been accepted and posted within the TDMS

Metadata: Descriptive information pertaining to a product (model, code, data, record, document, etc.). Metadata consist of information that characterizes the product and are used to provide information about the product. Metadata should provide sufficient information to catalog the information conveniently, facilitate its traceability, identify limitations or restrictions to its use, characterize the quality and the process by which it was developed or approved, and assist any potential user in the proper selection of information for a specific purpose.

Parameter: Scientific data that represent physical or chemical properties, consisting of an assigned variable name and generally represented by a value or range of values. Selected parameters that are potentially subject to varied interpretation and selection of multiple values, and subject to multiple use for various technical products, are subject to change control, and reside in the TDMS. Parameters from standard references, such as engineering handbooks, are accepted values and are not subject to the change control process.

Preliminary Submittals: Data acquired or developed using approved procedures that have not received a technical review (that establishes and documents the technical validity of the data.

Product Output: Output of an approved technical/model/analysis report that is a controlled source, subject to the requirements of the QARD document.

Qualified Data: Data collected under an approved QA program that meets the requirements of 10 CFR 60, Subpart G (i.e., qualified from origin), or unqualified data that have undergone the qualification process (QARD).

Raw Data: Field or laboratory data that have not been converted to or do not occur as scientific or engineering terms as identified in the online Technical Data Parameter (TDP) Dictionary. Raw data are not submitted to the TDMS.

Submittal Package: A package that consists of the data to be incorporated to the appropriate TDMS database, a completed Technical Data Information Form (TDIF), and a cover letter (i.e., letter of transmittal).

Technical Data Information Form (TDIF)–A form used to document reference information (metadata) related to data that are tracked in the LTDT database.

Technical Data Management System (TDMS): The platform that provides an arrangement of database components so related and connected as to form a unity (i.e., system) for identification and traceability of data and information.

Technical Data Parameter (TDP) Dictionary: An electronic dictionary of standardized technical terms that are used to identify the data.

Unqualified Data: Data not collected under an approved QA program that meets the requirements of 10 CFR 60, Subpart G (QARD).

7. REFERENCES

10 CFR 60, Energy: Disposal of High-Level Radioactive Waste in Geologic Repositories

Quality Assurance Requirements and Description, DOE/RW-0333P

AP-SIII.3Q, *Submittal and Incorporation of Data to the Technical Data Management System*

OSTI-LLNL-QIP-2.2, *Planning for Science Activities*

OSTI-LLNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures*

OSTI-LLNL-QIP-6.1, *Document Review*

OSTI-LLNL-QIP-16.0, *Condition Reporting and Resolution*

OSTI-LLNL-QIP-17.0, *Records Management*

OSTI-LLNL-QIP-SI.0, *Software Management*

OSTI-LLNL-QIP-SIII.0, *Scientific Notebooks*

OSTI-LLNL-QIP-SIII.1, *Technical Reports*

OSTI-LLNL-QIP-SIII.2, *Model Reports*

OSTI-LLNL-QIP-SIII.4, *Qualification of Unqualified Data*

OSTI-LLNL-QIP-SV.0, *Management of OSTI-LLNL Electronic Data*

8. ATTACHMENTS

Attachment 1 - OSTI-LLNL Key Technical Data Traceability Form

Attachment 2 - OSTI-LLNL Impact Review Action Notice

Attachment 3 -Criteria for the Technical Review of Data/Product Output

9. REVISION HISTORY

2/25/05 Revision 0, Modification 0:

   Initial Issue

10. APPROVALS

Preparer: *Leigh Gouveia*   Date: 2/25/05

Technical Reviewer: *QINHONG HU*   Date: 2/25/05

QA Reviewer: *VICTOR J. BARISH Jr*   Date: 2/25/05

Project Manager: *DAVID B. McCAULEN*   Date: 2/25/05

OSTI-LLNL Key Technical Data Traceability

Date: _____   Data Tracking Number: _____

Prepared By: _____

Title/Subject:

The following contain supporting documentation for the attached data submittal. These documents have been, or shall be submitted to OSTI-LLNL Records Center.

Notebooks/source documents:

ID#	Page Numbers

ID#	Page Numbers

ID#	Page Numbers

Photos:

ID (if possible)	ID (if possible)

Maps:

ID (if possible)	ID (if possible)

Computer Files are Listed on the Data Readme File.

Software Codes Used to Generate the Data are Listed on the Data Readme File.

Constraints, Caveats, Assumptions and Limitations are Listed on the Data Readme File.

Principal Investigator's Name	Signature	Date

Technical Data Coordinator's Name	Signature	Date

OSTI-LLNL
IMPACT REVIEW ACTION NOTICE

	1. QA: Page ___ of ___
2. Project Manager (print name):	3. Date:
4a. Principal Investigator (print name):	4b. Principal Investigator (signature):
	5. Reviewer (print name):

Review the documentation described below to determine the impact on data or technical/model reports. Document results below, indicating required actions to ensure consistency between inputs and data or technical/model reports or that no actions are required. Include document and revision numbers of technical/model reports to be revised.

6. Data to be Evaluated:	Title:	7. Complete Impact Review by: (Date)
	Data Tracking No:	□ Initial Issue □ Supersession □ Revision or Change □ Status Change □ Cancellation

8a. Impacted Document/DTN No.	Rev.	Impacted Document/Data Title	8b. Results of Impact Review

8c. Proposed Additional Work:

9a. Reviewer (print name)	9b. Reviewer (signature)	9c. Date:
10a. Principal Investigator/Project Manager (signature)		10b. Date:

INSTRUCTIONS FOR COMPLETING THE IMPACT REVIEW ACTION NOTICE (IRAN)

For all data supersessions and/or qualification status downgrades, query LTDT and DIRS to identify usage of the subject DTN. Prepare an IRAN for each user of the DTN.

Technical Data Coordinator:

1.   Enter the QA designator as listed on the TDIF for the DTN.

2.   Print the name of the OSTI-LLNL Project Manager.

3.   Enter the date initiated.

4a.   Print the name of the Affected Principal Investigator (PI), if impacted data/documents were identified, or indicate none identified, if applicable.

Blocks 4b, 5, and 7 through 11 are not applicable if no impacted data/documents were identified.

Affected PI:

4b.   Enter signature.
5.   Enter the designated reviewer's name, if other than the Affected PI.

Technical Data Coordinator:

6.   Enter a complete description of the document/data to be evaluated for impact, as indicated by the labeled entry spaces. Indicate whether the document/data was an initial issue, revision, change, supersession, status change, or cancellation. If multiple technical product(s) are to be reviewed on the same IRAN, a listing of the technical/model report(s) titles and numbers may be attached to the IRAN.

7.   Enter the date for completion of the impact review (recommended minimum is three days).

8a.   Enter the Document Identifier, revision number, and title of the impacted, or potentially impacted, technical/model report(s) or developed data DTN(s).

Reviewer:

8b.   Enter a concise, clear statement of the results of the impact assessment for each technical/model report or data listed in Block 8a. Include recommended actions and proposed completion dates, if impacted, or indicate not impacted, if applicable.

8c.   Identify any proposed additional work that may be required as a result of the impact to the data or technical/model report(s).

Reviewer (if other than the Affected PI):

9.   Print name (Block 9a), sign (Block 9b) and date (Block 9c).

Affected PI/Project Manager:

10.   Enter signature ((Block 10a) [If the Affected PI was the reviewer, the Project Manager (or designee) shall sign in this block] and date (Block 10b).

CRITERIA FOR THE TECHNICAL REVIEW OF DATA/PRODUCT OUTPUT

1. Do the Data/Product Output meet the requirements for accuracy, precision, and representativeness identified in the planning document for the investigation?

2. Are the Data/Product Output clearly identified and traceable?

3. Does the Data/Product Output appear correctly presented and reasonable for the methods identified in the planning document or procedures used to generate the submittal?

4. Are the Data/Product Output legible and adequately labeled with respect to units, axis labels, etc.? (Note that spreadsheets or other computer outputs may not label the units, in which case this information could be provided as supplementary information accompanying the submittal).

5. If other previously reported submittals or submittals from other sources are present along with the new submittal being reviewed, are these clearly separated or distinguishable?

6. Is the quality assurance status of the Data/Product Output:

   a) Identified by information supplied with the submittal package if no DTN has been issued?

   b) Traceable to information supplied with the submittal package if a DTN has been issued (i.e., the DTN number provides a link to the QA status)?

7. Are calculations correct and described in sufficient detail to permit reproduction by the reviewer?

8. Is computer software used adequately identified, documented, and controlled in accordance with OSTI-LLNL-SI.0, *Software Management* or other applicable Yucca Mountain Project procedures?

9. Are the following complete and accurate?

   a) Description of the work as it was performed?

   b) Results obtained?

   c) Names of the persons performing the work?

10. Are there any anomalies or typographical errors apparent in the Data/Product Output? Confirm that files have not been corrupted by comparing file size, file modification dates, and spot-checking.

11. Are restrictions and limitations identified?